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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 10/025,966  | 12/21/2001  | Steven Rosen         | UCAL-230                | 2216             |
| 24353   | 7590        | 03/02/2004           | EXAMINER                |                  |
| BOZICEVIC, FIELD & FRANCIS LLP<br>200 MIDDLEFIELD RD<br>SUITE 200<br>MENLO PARK, CA 94025 |             |                      | SLOBODYANSKY, ELIZABETH |                  |
|   |             |                      | ART UNIT                | PAPER NUMBER     |
|   |             |                      | 1652                    |                  |

DATE MAILED: 03/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/025,966

### Applicant(s)

ROSEN ET AL.

### Examiner

Elizabeth Slobodyansky, PhD

### Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/22/02; 10/15/02;
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-22 are pending.

#### ***Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-3, SEQ ID NO:6, in Paper filed November 7, 2003 is acknowledged. The traversal is on the ground(s) that "As stated in the MPEP § 803, if search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. It is Applicants' position that it would not be unduly burdensome to perform a search on claims 1-22 together. Accordingly, Applicants traverse the restriction requirement". This is not found persuasive because the examination of all groups together would require search of at least classes/subclasses 424/94.6; 435/6, 7.1, 19, 252.3, 320.1, 325; 514/789; 530/388.1, 536/23.2, 23.5 as well as patent and non-patent databases and would require divergent considerations. Applicants further requested rejoinder of method claims to the extent that they incorporate all the limitations of an allowed claim, as provided for under MPEP § 821.04". Such rejoinder will be made when the product claim will be allowable.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups II-VIII, there being no allowable generic

or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed November 7, 2003.

Claims 1-3 are under consideration.

### ***Specification***

The specification is objected to because it does not comply with the Sequence Rules. 37 CFR 1.821(c) requires that each sequence that appear in the specification being assigned a sequence identification number, i.e. SEQ ID NO. However, in the instant specification the same sequence is being assigned two SEQ ID NOs. For example, SEQ ID NO:6 is 100% identical to SEQ ID NO:15, SEQ ID NO:12 is 100% identical to SEQ ID NO:18.

Correction in the specification and the Sequence listing are required.

### ***Claim Objections***

Claim 3 is objected to as reciting non-elected SEQ ID NOs: 3, 9, 12, 15 and 18.

Appropriate correction is required.

Furthermore, it is customary to write SEQ ID NO:3 not SEQ ID NO:03.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of polypeptides having glucosamine-6-sulfatase activity. The genus of said polypeptides encompasses any polypeptides having glucosamine-6-sulfatase activity from any source, both naturally occurring and man made. This includes enzymes encoded by the same genes and different genes. With regard to the genus of human glucosamine-6-sulfatases, said genus encompasses glucosamine-6-sulfatases encoded by the same and different genes and allelic and splice variants thereof. The specification teaches the structure of only a single representative species of such glucosamine-6-sulfatases, a polypeptide having the amino acid sequence of SEQ ID NO:6. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of having glucosamine-6-sulfatase activity. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al.

Tang et al. (WO200159127 A2, form PTO-1449 filed April 22, 2002) teach an enzyme having an amino acid sequence that is 100% identical to SEQ ID NO:6 of the instant invention.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al.

Tang et al. (WO200157190-A2, A\_Geneseq Database, accession AAM 79215, form PTO-1449 filed April 7, 2003) teach an enzyme having an amino acid sequence that is 100% identical to SEQ ID NO:6 of the instant invention.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by.

Robertson et al.

Robertson et al. (Biochem. J., 288, 539-544, 1992) (form PTO-1449 filed April 22, 2002) teach human glucosamine-6-sulfatase having the amino acid sequence that is 18.1% identical to SEQ ID NO:6 of the instant invention.

### ***Conclusion***

The post filing art made of record and not relied upon is considered pertinent to applicant's disclosure.

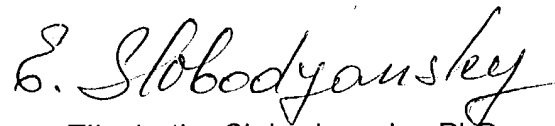
Morimoto-Tomita et al. (2002) J. Biol. Chem., 277, pages 49175-49185 teach human sulfatase Hsulf-2 having the amino acid sequence that is 100% identical to SEQ ID NO:6. This is the work of the inventors' Group.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "E. Slobodyansky". The signature is fluid and cursive, with the first letter "E" being large and stylized.

Elizabeth Slobodyansky, PhD  
Primary Examiner  
Art Unit 1652

February 20, 2004